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10/783,379

02/19/2004

William S. Hurst

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11/27/2006

BAXTER HEALTHCARE CORPORATION

1 BAXTER PARKWAY

DF2-2E

DEERFIELD, IL 60015

EXAMINER

SCHATZ, CHRISTOPHER

ART UNIT

PAPER NUMBER

1733

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/783,379

Applicant(s)

HURST ET AL.

Examiner

Christopher T. Schatz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,21-34,36-47,49-55,57,58 and 77-80 is/are pending in the application.
- 4a) Of the above claim(s) 4,6-9,24,29,31-34,36,40,43 and 52-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,21-23,25-28,30,37-39,41,42,44-47,49-51,57,58 and 77-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## FINAL REJECTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3, 5, and 77-80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for exposing the bond area of the interface area to infrared energy, does not reasonably provide enablement for exposing the non-bond area of the interface area to infrared radiation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to understand the invention commensurate in scope with these claims. Claim 1 requires that the interface area comprise a non-bond area and a bond area and a heat shield be placed over the interface area. The claim further requires "exposing the interface area to infrared energy." Because the interface area consists of both the non-bond area and the bond area, the limitation requires that the non-bond area be exposed to infrared energy. Such a limitation is not enabled because nothing in the specification directs one of ordinary skill in the art to understand how a non-bond area of the interface is exposed to infrared energy when said non-bond area is protected with a heat shield.
3. Claim 77 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim requires that the “heat shield constrain the bond area to maintain a desired functional geometry of the bond area.” In paragraph 0108 of the specification applicant discusses maintaining functional geometry. However, the specification only states that constraining the bond area with the heat shield helps to the functional geometry of the *components*. Nothing in the specification supports claim 77 which requires that the functional geometry be maintained specifically in the bond area.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5, and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Peters et al. ‘552.

Peters et al. discloses a method for assembling a medical device comprising: providing a first article of a polymeric material; providing a second article of a polymeric material; contacting the first article with the second article along an interface area; the interface area comprising a bond area and a non-bond area; fitting a heat shield over the interface area (abstract, column 2, lines 64-67); exposing the interface area to infrared energy in order to generate sufficient heat to create a bond between the first article and the second article (figure 5a-5f, column 8, lines 6-56, column 9, lines 7-15). As to claim 5, Peters et al. discloses a method wherein the two articles are medical tubing. As to claim 78, Peters et al. discloses a method

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further comprising using the heat shield to prevent exposure of the non-bond area to infrared energy.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 77, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al.

Peters et al. discloses a method as discussed in claim 1 above, and the reference further discloses a method wherein the heat shield constrains the bond area (column 2, lines 64-67). The reference is silent as to maintaining a desired functional geometry, but examiner asserts that maintaining the functional geometry of the articles being bonded is highly desired, and it would have been obvious to one of ordinary skill in the art at the time the invention was made that using a heat shield to constrain the bond area would aid in maintaining the desired geometry of the articles. As to claim 78, it would have been obvious to one of ordinary skill in the art at the time the invention was made that using a heat shield would negate distortion at the interface area because the shield protects the non-bond area of the interface area. As to claim 80, it would have been obvious to one of ordinary skill in the art at the time the invention was made to surround the interface area with the heat shield because the non-bond area in the method of Peters extends

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around both of the articles (or tubes) being bonded, and one of ordinary skill in the art would have readily recognized the necessity of protecting the entire non-bond area.

7. Claims 3, 21, 25-28, 30, 37, 38, 41, 42, 44-47, 49-51, and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. '552 in view of Holman et al. (2003/0201059).

Peters et al. discloses a method for assembling a medical device comprising: providing a first article of a polymeric material; providing a second article of a polymeric material; contacting the first article with the second article along an interface area; the interface area comprising a bond area and a non-bond area; fitting a heat shield over the interface area, the heat shield permitting transmission of infrared energy to the bond area (abstract, column 2, lines 64-67); and bonding the first article to the second article along the bond area using infrared exposure (abstract, figure 5a-5f, column 8, lines 6-56, column 9, lines 7-15).

Peters et al. is silent as to a method of applying an infrared absorbing pigment to the first and second articles. Holman et al. discloses a method of assembling two medical tubular articles together as discussed above, and further discloses a step of applying an infrared absorbing pigment to the first article and the second article to define an interface area (paragraph 0037-0039). Holman et al. also discloses that an infrared responsive pigmented film 18 can be placed between the first article and second article to define an interface area (paragraph 0039).

Application of said pigment coating or film provides each article with a desired absorption characteristic (paragraph 0035-0037). At the time of the invention it would have been obvious to a person of ordinary skill in the art to modify the method of Peters et al. by applying an infrared absorbing pigment (as a coating or film) to the first article and the second article to define an

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interface area as taught by Holman et al. above. Such a modification would enable the absorption characteristics of the articles of Peters et al. to be varied to a desired characteristic.

As to claims 25 and 44, examiner asserts that printing is a well-known method of coating an article, and one of ordinary skill in the art would have readily appreciated printing the coating onto the first and second articles. Applicant is notified that because applied failed to traverse examiner's Official Notice with respect to claims 25 and 44, examiner's statement that printing the coating onto the first and second articles is now taken to be admitted prior art. MPEP 2144.03. As to claims 26-28 and 45-47, Holman et al. discloses a method wherein the infrared absorbing pigment is placed on a first portion of the first or second article in a first concentration and in a second portion of the surface in a second concentration lower than the first concentration; applying a first infrared exposure to the first portion of the surface to create a seal, and applying a second infrared exposure higher than then the first infrared exposure to the second portion of the surface to create a second seal (paragraphs 0058-0067, 0034-0045, 0013-0018, figure 14). As to claims 3, 37, 49, and 57 examiner asserts that PTFE is a well-known material in the art, and one of ordinary skill in the art would have readily recognized its use as an infrared blocker. Applicant is notified that because applied failed to traverse examiner's Official Notice with respect to claims 3, 37, 49, and 57, examiner's statement that PTFE is a well-known material in the art is now taken to be admitted prior art. MPEP 2144.03. As to claims 38 and 50, Peters et al. discloses that bonding takes place as a result of infrared absorption at multiple locations along an axis (locations 40, 41, 38, 39). Since the reference discloses that the heat shield blocks non-bonding regions from infrared exposure, the presence of "slots" at locations

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40, 41, 38, 39, is inherent to the heat shield of Peters et al. because said locations are exposed to infrared light.

8. Claims 21-23 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. and Holman et al. as applied above, and in further view of Ammann et al. '097.

Peters et al. and Holman et al. disclose a method as discussed above, and further Holman et al. further discloses that any known infrared absorbing pigment can be used. The references are silent however, as to specifically using carbon black or activated charcoal. Ammann et al. discloses a method for assembling a medical device comprising: providing first and second articles of polymeric material, contacting the first article with the second article along the interface area and bonding the two articles together using infrared radiation (figure 2, column 2, line 40 – column 4, line 8). Ammann further discloses that it is well known and preferable to use carbon black or activated charcoal as the infrared absorbing pigments at the bonding interface (column 3, lines 5-10). At the time of the invention it would have been obvious to a person of ordinary skill in the art to use either carbon black or activated charcoal as the applied infrared absorbing pigment as is well known in the art and taught by Ammann et al.

As to claim 39, Ammann et al. discloses a method wherein bonding is performed using an infrared lamp (column 3, line 63 – column 4, line 7).

### ***Response to Arguments***

Applicant's arguments filed September 7, 2006 have been fully considered but they are not persuasive. As to the species restriction, applicant's argument that claim 1 is generic to all the species is not germane to the species restriction. Applicant is respectfully notified that claim



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I was never restricted from the application, rather, several of the dependent claims were restricted from each other. Applicant does not present arguments as to why the independent and distinct species identified in the Office Action mailed in November 25, 2005 are not mutually exclusive. Applicant should further note that in the office action mailed on June 15, 2006 the species restriction was made final and thus prosecution on the manner is closed.

Applicant argues that Peters does not disclose that the heat shield is fitted over the balloon waist. Examiner asserts that Peters need not disclose that the heat shield cover the balloon waist in order to meet the limitations of the claims. Applicant's claims as currently written only require that the heat shield be placed over the interface which comprises the non-bond area and bond area. The claim *does not require* that the heat shield be placed over the *entire* interface, and because Peters et al. discloses a heat shield over the non-bond area of the inter face, the reference meets the limitations of the claims.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37


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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

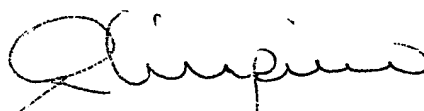
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher T. Schatz** whose telephone number is **571-272-1456**. The examiner can normally be reached on 8:00-5:30, Monday -Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher T. Schatz



RICHARD CRISPINO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700